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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,979	05/21/2004	Steven M. Ruben	PZ028P2C1	8748

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/849,979	RUBEN ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-48* is/are pending in the application.

4a) Of the above claim(s) *48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 25-48 are pending in the instant application. Claim 48 is drawn to a non-elected claim. Claims 25-47 are under consideration by the Examiner.

2. Receipt of applicant's arguments filed on 7/12/2006 is acknowledged.

3. Applicants arguments filed on 7/12/2006 have been fully considered but were non-persuasive. The issues remaining are stated below.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

5. Claims 25-47 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection is maintained for reasons of record set forth at pages 2-6 of the previous Office action (4/28/2006).

Applicants argue that the test for specificity under 35 USC 101 is whether an asserted utility is specific to the subject matter claimed and accordingly the disclosure that the instant invention is useful in treating, preventing, detecting and/or diagnosing neural and neurodegenerative disorders is specific as not every antibody may be used to treat, prevent, detect and/or diagnose a neural and/or neurodegenerative disorder. Therefore, Applicants argue that the skilled artisan would most certainly not consider such a use to be a "throw-away utility" such as a landfill. However, contrary to Applicants arguments, it is unclear from the specification and Applicants arguments whether the protein of the instant invention or antibodies to the protein of the instant invention may be used to treat or prevent a neural and/or

neurodegenerative disorder. Furthermore, such an asserted utility is not a specific utility because such a utility cannot be accepted in the absence of supporting evidence. There is little doubt that, after complete characterization, this antibody to a protein of amino acid sequence set forth in SEQ ID NO:139 protein will probably be found to have a patentable utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicants claimed invention is incomplete.

The instant claims are drawn to an antibody to a protein of as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as expressed in the front cortex of the brain, the instant invention is incomplete. In the absence of a knowledge of the biological significance of the protein to which the antibody is specific for, there is no immediately obvious "patentable" use for the antibody. To employ the antibody of the instant invention in treatment of neural and neurodegenerative disorders is clearly to use it as the object of further research which has been determined by the Courts to be a non-patentable utility. The employment of the claimed antibody in treatment of neural and neurodegenerative disorders is not a substantial or specific utility, because the polypeptide to which the antibody binds is not associated with a specific disease and there is no evidence on the record that it is associated with any diseases. Such utilities are analogous to the assertion that a particular DNA can be employed as a molecular weight marker, which is neither a specific or substantial utility.

Applicants argue that Applicant discloses a biological activity (e.g., "Elevated expression of HHPEN62 within the frontal cortex of the brain indicates that it "may" be involved in neuronal survival; synapse formation; conductance; neuronal differentiation, etc," See, page

86, paragraph 0197), and reasonablv correlates that activity to a disease or condition e.g., inter alia, neuronal and neurodegenerative disorders), the applicant has sufficiently identified a specific utility for the invention. M.P.E.P. 2107 I(A) at 2100-32. However, contrary to Applicants arguments, there is no correlation between the asserted activity and the asserted use. The disclosure recites that because there is elevated expression of HHPEN62 within the frontal cortex of the brain indicates that it "may" be involved in neuronal survival. This asserted utility is credible but is not specific or substantial. In particular, the specification does not state what role the HHPEN62 protein may play in neuronal survival or neuronal differentiation or how the HHPEN62 protein modulates neuronal survival or neuronal differentiation. The specification provides no nexus between any particular neuronal or neurodegenerative disorder and any specific change in HHPEN62 form or quantity. Since significant further research would be required before the antibody to HHPEN62 could be used in a real-world treatment of a specific disease, the asserted utility is not substantial.

Applicants argue that the specification discloses that the instant invention maps to chromosome 18q22-23, a chromosomal region identified in the art as a susceptibility loci for neuronal and neurodegenerative disorders including bipolar affective disorder and have cited Nothen et al (1999) in this regard. However, contrary to Applicants arguments, one of skill in the art would not be convinced that the asserted utilities are specific since Applicants have not presented evidence that the instant protein (to which the claimed antibody is specific for), has anything to do with neural or neurodegenerative disease or any other disease or condition or that an alteration in this protein has anything to do with any disease or condition.

Applicants argue that the specific utilities are substantial and useful for a particular practical purpose wherein Applicants disclose a therapeutic method of treating a known disease, such as neuronal and neurodegenerative diseases. However, contrary to Applicants arguments, the specification does not provide a nexus between a disease state and an alteration in forms or level of the protein. Again, the specification asserts that the elevated expression of the HHPEN62 within the frontal cortex "may" be involved in neuronal survival, synapse formation, conductance, neuronal differentiation, etc. (page 86, para 0197) but does not state what the pharmacological activity of HHPEN62 is, does not state the role of the protein, or how the levels or form of the protein are changed in the disease state. Therefore, the assertion that the protein can be used in treatment is not a specific or substantial utility.

Applicants argue that they do not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty or provide actual evidence of success in treating humans where such a utility is asserted. However, contrary to Applicants arguments, the Office Action has not required proof that a correlation exists between a particular activity and an asserted therapeutic use or evidence of success in treatment. The Office Action has provided an analysis of the disclosure and set forth the findings that the totality of the disclosure does not meet the requirements of 35 USC 101 for a specific, substantial or well-established utility. It is pointed out that an asserted utility must meet the three-pronged test of being credible, specific and substantial. As discussed n the rejection set forth above, none of the asserted utilities satisfy all three prongs. The skilled artisan would have to conduct significant further research to determine the particular function of the

HHPEN62 protein in order to identify a specific and substantial utility for this new protein. In such a case, the asserted utility is not substantial.

Claim Rejections - 35 USC § 112, first paragraph

6. Claims 25-47 are also rejected under 35 U.S.C. 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 6-7 of the previous Office action (4/28/2006).

Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification does not disclose a biological activity for the protein to which the claimed antibody is raised, therefore, there is no specific and substantial asserted utility or well established for the claimed antibody to the protein of amino acid sequence set forth in SEQ ID NO:139.

Conclusion

No claim is allowed.

Claims 25-47 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
July 18, 2006